

Remarks

Status of the Claims

Claims 1-33 have been canceled without prejudice or disclaimer. Claims 34-220 have been withdrawn as drawn to non-elected inventions or species. New claims 221-232 have been added. Claims 34-232 are currently in the case. The newly added claims are drafted for further clarity and do not contain any new matter.

All the new claims read on the elected group I.

Rejections Under 35 USC 112

The Action rejects claims 19-23 as indefinite for use of the term "reduced keratin." Those claims have been canceled without prejudice rendering the rejection moot.

Rejections Under 35 USC 103

The Action rejects claims 1-6 as obvious over Ken (US 20030004568). Applicants submit that the reference neither teaches nor suggests the subject matter of canceled claims 1-6, nor does it teach or suggest any of the newly added claims 221-232.

The Action also rejects claims 1-33 over Hammer ((US 20030220700) in view of Van Dyke (6,371,984) or Suita-Mangano (EP 0298684) and Savaides (US 5617883). Neither do any of these references, either alone or in combination teach the inventions of canceled claims 1-33 or newly added claims 221-232.

The Action takes the position that the cited art contains all the elements of the claimed inventions and that the inventors could have simply selected known elements from a finite list of possible components to construct the claimed devices, wherein each component would serve its expected function.

The Action, however, does not consider the surprising and unexpected results achieved by the current claimed inventions. The claimed orthopedic devices are coated with keratin that accelerates the formation of bone matrix in the presence of osteoblasts. Keratin is thus not just an equivalent of the other biological polymers listed in cited art such as collagen or silk, for example, that could be selected to achieve the expected and predictable result, but provides an unexpected and surprising result when coated onto an implant that is used in the presence of osteoblasts as is an orthopedic implant.

An invention that otherwise appears obvious from the prior art, may not be obvious if it produces results that are unexpected to one of ordinary skill in the art in view of the prior art. For example, the Federal Circuit has recently addressed the use of unexpected results to rebut an obviousness case: *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*; 492 F.3d 1350 (Fed. Cir. 2007).


In *Takeda*, the Federal Circuit held that Takeda's claims covering pioglitazone were not invalid as obvious over a prior art compound known as "compound b." Among other things, the Federal Circuit focused on the fact that the patent holder's specific placement of an ethyl component created unexpected results regarding lack of toxicity. The court considered a report containing results of preliminary toxicity studies that involved selected compounds, including pioglitazone and compound b. Compound b was shown to be "toxic to the liver, heart and erythrocytes, among other things," whereas pioglitazone was "comparatively potent" and "showed no statistically significant toxicity." Takeda had also performed additional toxicity and potency studies on fifty compounds that had been already synthesized and researched by Takeda, including pioglitazone. Pioglitazone was the only compound that exhibited no toxicity, despite the fact that many of the other compounds were found to be more potent.

As in *Takeda*, the use of a known product is not obvious if one achieves an unexpected result. Because the claimed implants do achieve a result that was not predictable or expected based on the prior art, the claims cannot be legally obvious.

The Examiner is respectfully requested, therefore, to withdraw all rejections over the cited art.

It is Applicant's belief that all the Examiner's concerns have been addressed by the preceding amendments and discussion. The claims are now in condition for immediate allowance. If the Examiner has any questions or suggestions as to how the claims might more quickly proceed to allowance, a telephone call to the undersigned representative at 512.542.8446 is welcomed.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Timothy S. Corder", is written over a horizontal line.

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